U.S. FOOD & DRUG ADMINISTRATION

Center for Drug Evaluation and Research (CDER)

FDA CDER NextGen Portal

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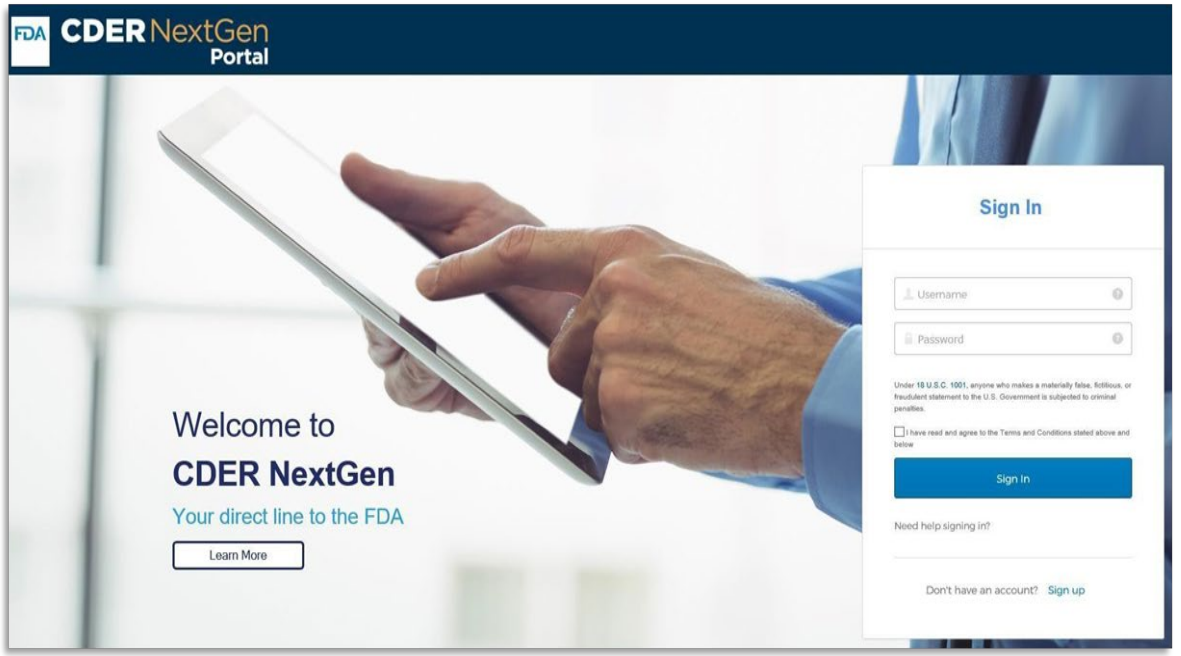
Agenda

- CDER NextGen Portal
- Before and After NextGen Portal
- What is New ?
- User's Adoption



FDA Disclaimer

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CDER NextGen Portal

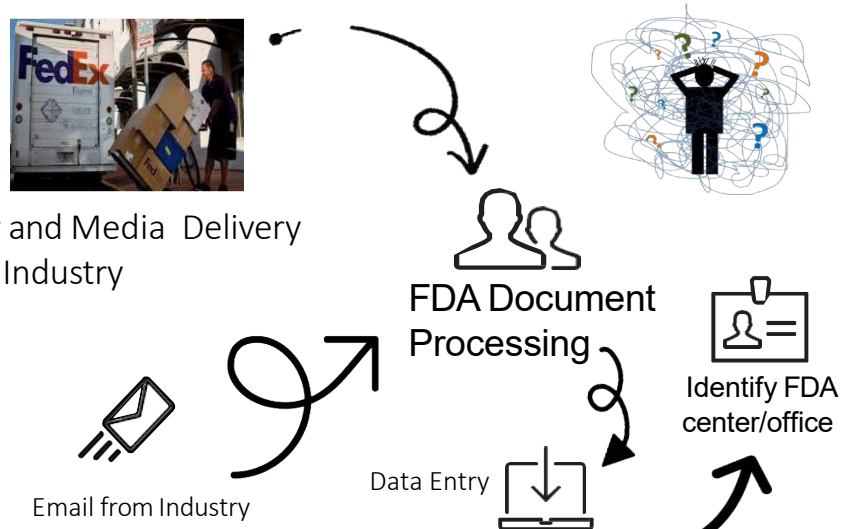
One stop shop for the purpose of **non-eCTD Submission**, Collaboration and Reporting. The Portal continues to reduce regulatory overhead for sponsors, academia, research institutes, and small businesses.

CDER NextGen Portal

Digital Transformation

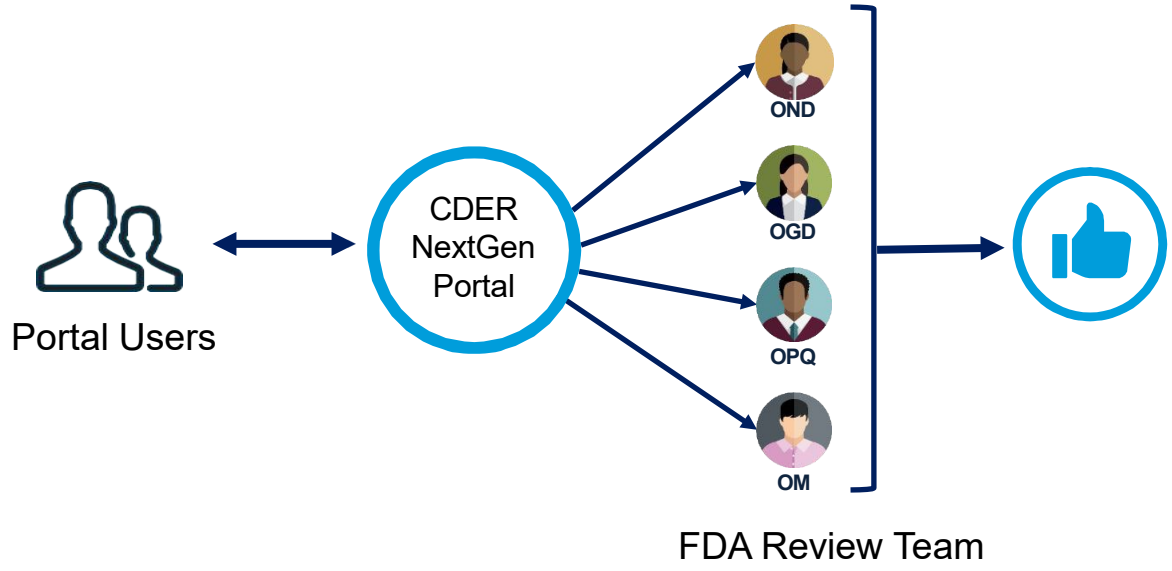
in action to promote safe and effective human drug review and approval

Before NextGen Portal



Digital Transformation

After NextGen Portal



- Inefficient paper and Media processing
- Manually intensive and inefficient

- Streamlined submissions with clean, complete, and validated data
- Maximized API lead technology enablement to improve efficiency
- Improved collaboration between the FDA and Stakeholders

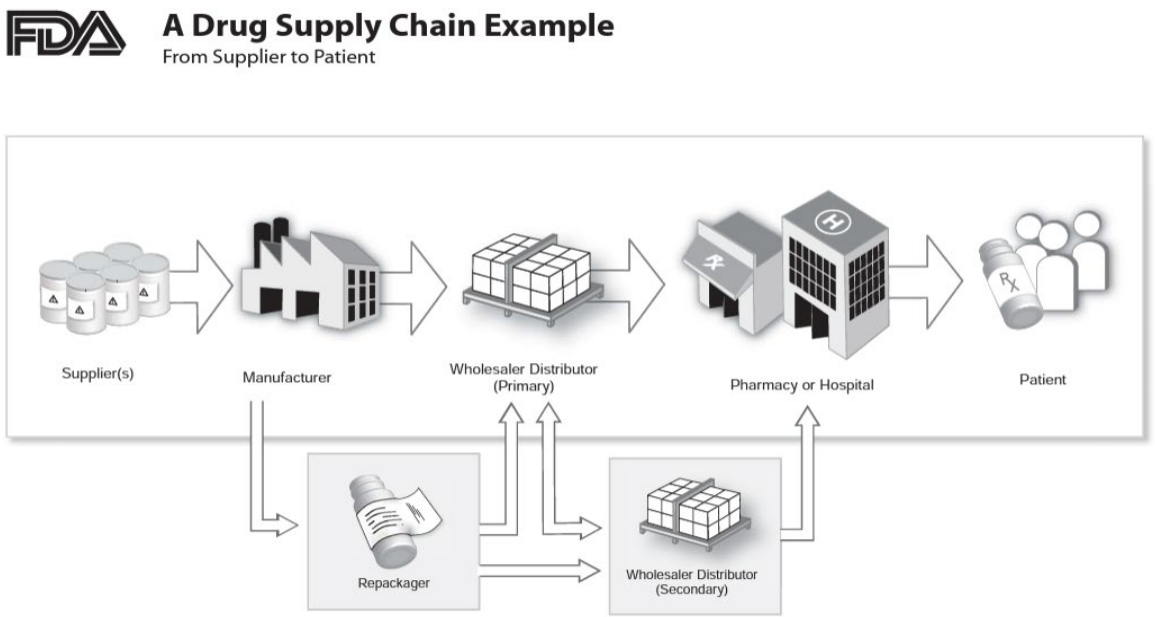
FDA CDER NextGen Portal Products

	Regulatory Submission	Streamlined Collaboration	Congressional Reporting
Drug Shortages Notifications			✓
Research IND Application Builder	✓		
CARES Volume Act Reporting	✓		✓
Alternate Submissions (Non eCTD Type III DMFs, EUA and others)	✓		
Orphan Drug	✓	✓	
Drug Development Tools	✓	✓	
Controlled Correspondence		✓	
Pre-ANDA & CPAM Meeting Request		✓	
Pre-Assignment Number	✓	✓	
Waiver Exemption Exceptions Request	✓	✓	
Program Fee		✓	✓
Standards Recognition			✓
Extensions Requests			✓
Manufacturing Capacity			✓
Critical Care Drug Monitoring Portal			✓
Radioactive Drug Research Committee		✓	
Potential Drug Shortage		✓	
Emergency Use Potential Drug Shortage	✓	✓	
Pre-Launch Activities Importation Requests		✓	
OMUFA	✓	✓	✓
Statement of Investigator (Form FDA 1572)	✓		

CDER NextGen Portal What is New?

Drug Supply Chain Security Act (DSCSA) Portal

Steps to achieve interoperable, electronic tracing of products at the package level
to identify and trace certain prescription drugs as they are distributed in the United States.



Enabled Trading Partners to report and respond :

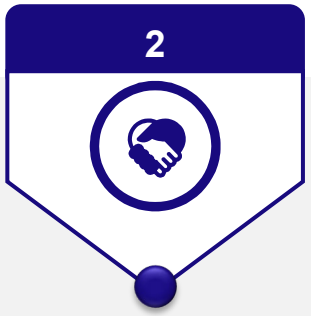
- Transaction Information (TI)
- Transaction Statement (TS)
- Information Request (IR)

Over-The-Counter Monograph Drug User Fee Program (OMUFA)

Initial Enablement

September 2022

- Deployed within the CDER NextGen Portal to streamline the user fee program



First Submission

September 2024

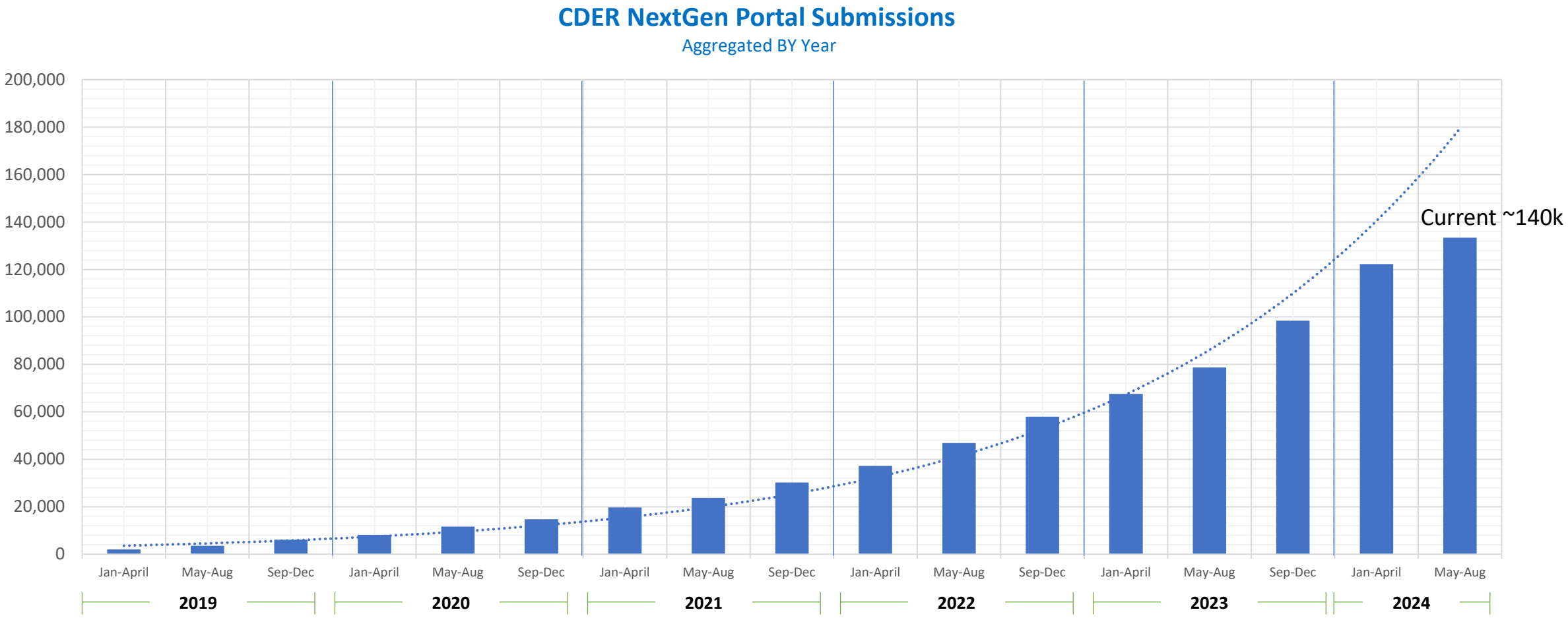
- FDA CDER received the first submission from industry as a critical milestone to the OMFUA Program

Upcoming Enhancements

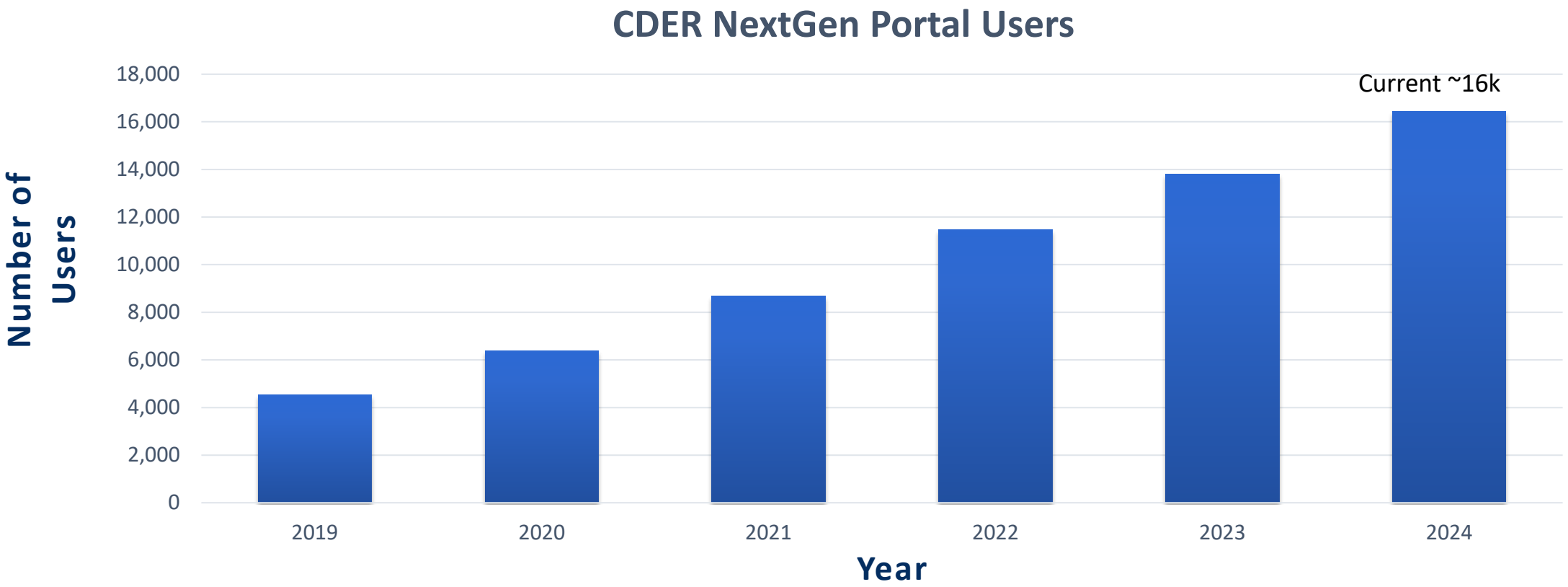
January 2025

- Enabling sequential OMUFA Meeting IDs
- Submission comments logged as a PDF
- Enhance user experience

Submissions on the NextGen Portal



NextGen Portal Users over the last 6 years



CDER NextGen Portal Impacts on the regulatory process

1. Improved Efficiency: Streamlined submissions, reducing the time and effort required for regulatory processes.

2. Enhanced Communication: Facilitates secured messaging within the portal between applicants and FDA reviewers.

3. Greater Transparency: The portal offers a consolidated detailed view of submission history.

Need Support ?

Contact edmsupport@fda.hhs.gov

Thank You!!